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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/417,448	10/13/99	MCCAFFERTY	J 28111/32729B

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1627	2

DATE MAILED: 01/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/417,478	McCafferty et al
Examiner	**Group Art Unit**
P. Ponnaluri	1627

☒ Responsive to communication(s) filed on *Oct 13, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *44-53* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *44-53* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *07/971,857* .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application is a division of application serial number 08/484,893, which is a continuation of application serial number 07/971,857, which is a 371 of PCT/GB91/01134.

2. The preliminary amendment filed on 10/13/99 has been fully considered and entered into the application.

3. Claims 1-43 have been canceled and new claims 44-53 have been added by the amendment filed on 10/13/99.

4. Claims 44-53 are currently pending in this application and claims 44-53 are being examined in this application.

5. The specification on page 1, should be amended to reflect the status of the parent application 07/971,857, which is now US Patent 5,969,108.

Drawings

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicant is invited to notice that boxes 2, 6 and 12 were checked by the draftsman in PTO 948. Applicant is encouraged to amend the specification so that the description of renumbered figure corresponds to the renumbered figures.

Specification

7. The use of the trademarks STRATACLEAN (in page 173, line 14) and MILLIPORE (in page 183, line 4) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

9. Claim 45 is objected to because of the following informalities: in claim 45, 'in vitro' is underlined, which is not clear whether the underlining is intended to appear in the patent . The underlining is commonly used to indicate amendments or changes in the claims and is normally not intended to be printed in the published patent. If underlining is intended to appear in the claims in the published patent, applicant should clearly indicate or rewrite 'in vitro' in italics.

Claim Rejections - 35 U.S.C § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 44-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 44 is vague and indefinite by reciting 'host cells harboring a library of nucleic acids', It is not clear what does applicant mean by harboring. Does applicant mean containing. Applicants are requested to clarify. It is also not clear what does applicant mean by host cells harboring a library of nucleic acids. Does applicant mean that each host cell contains a library or each host cell contains a single nucleic acid fragment encoding a specific binding pair member. Applicants are requested to clarify. Claim 44 is vague and indefinite by reciting 'type of member of a specific binding pair', what does applicant mean by type of member. Which type of member, applicants are requested to clarify.

Claim 44 recites the limitation "said specific binding pair members" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 is vague and indefinite by reciting 'in functional form', it is not clear what does applicant mean by displayed on the surface of bacteriophage in functional form. It is not clear what function, applicants are requested to clarify. Does applicant mean that the specific binding pair is displayed on the outer surface of the phage and anchored to the phage coat through gene III. Applicants are requested to clarify.

Claim 44 is vague and indefinite by reciting '..... said specific binding pair members are displayed on surface of bacteriophage particles in functional form comprising a binding domain for

a complementary specific binding pair member and genetic material of each particle displaying a specific binding pair member encodes the associated displayed specific binding pair member..', it is not clear whether applicants mean that the specific binding pair member displayed on the surface of bacteriophage particle comprises a binding domain which is complementary to a specific binding pair member or the specific binding pair member displayed on the surface of the bacteriophage particle comprises a domain which is complementary to a specific binding pair displayed on the surface of another phage particle.

Claim 44 is vague and indefinite by reciting '...and genetic material of each particle displaying a specific binding pair member encodes the associated displayed specific binding pair member...', It is not clear what does applicant mean by the associated displayed specific binding pair. It is not clear whether applicants mean that the genetic material of each bacteriophage particle encodes the displayed specific binding pair or the genetic material of each bacteriophage particle encodes the associated specific binding pair member which is associated to the specific binding pair member. Applicants are requested to clarify. There is insufficient antecedent basis for 'the associated displayed specific binding pair member' in the claim. Claim 44 is vague and indefinite by reciting '...which uses a helper phage for packaging into said particles..', it is not clear what does applicant mean by which uses, does applicant mean that the plasmid nucleic acid uses a helper phage for packaging into said particles. Applicants are requested to clarify. Claim 44 is vague and indefinite by reciting 'a said fusion', applicants are requested to amend the claim as "said fusion".

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 44-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 7, 21 and 29 of of U.S. Patent No. 5,969,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed recombinant host cells comprise a library of nucleic acid fragments comprising a type of specific binding pair, and the specific binding pair of the instant claims read on the specific binding pair member which is a single polypeptide chain comprising a

binding domain of an antibody of the reference. The reference teaches a method of producing a member of a specific binding pair member, which member is a single polypeptide chain comprising a binding domain of an antibody using recombinant host cells (refers to the recombinant host cells of the instant claims), and the method comprises expressing in recombinant host cells nucleic acid encoding said specific binding pair member, the specific binding pair member is expressed as a fusion with a component of a secreted replicable genetic display package which displays said specific binding pair at the surface of the package component. The genetic material of the package (refers to genetic material of the bacteriophage particle of the instant claims) displays a specific binding pair member encoding said specific binding pair member, and the specific binding pair member is expressed from a phagemid (refers to the genetic material being phagemid of the instant claims) as a capsid fusion protein and a helper phage (refers to the nucleotide sequence encoding the fusion which uses helper phage of the instant claims) or a plasmid expressing complementing phage genes and capsid fusion to package the phagemid nucleic aid (see claim 4, in particular). The reference teaches that the genetically diverse population is obtained from,

a) a repertoire of rearranged immunoglobulin genes of an animal immunized with complementary specific binding pair member (reads on the genetically diverse population of the instant claim 48);

b) a repertoire of rearranged immunoglobulin genes of an animal not immunized with complementary specific binding pair member (reads on the genetically diverse population of the instant claim 49) (see claim 7, in particular). The reference also teaches recombinant host cells harboring a library of nucleic acid fragments comprising fragments encoding a genetically diverse

population of a type of member of a specific binding pair which member is a single polypeptide chain comprising a binding domain of an antibody which read on the recombinant host cells harboring a library of nucleic acid fragments comprising fragments encoding a genetically diverse population of a type of a member of a specific binding pair. The reference differs from the claimed invention by reciting that the specific binding pair member is a single polypeptide chain comprising a binding domain of an antibody. The specific binding pair member of instant claims is broad and reads on the immunoglobulin binding domain of the reference. However, the reference discloses that the type of specific binding pair are antigen-antibody, biotin-avidin, hormone-hormone receptor, receptor-ligand, enzyme-substrate, and IgG-protein A (see column 11, lines 1-3). Thus, it would have been obvious to a person of ordinary skill in the art to use different types of specific binding pair members in the recombinant host cells because the reference teaches the recombinant host cells comprising a single polypeptide chain comprising a binding domain of an antibody and a method of producing a member of a specific binding pair using phagemids.

The claimed invention of claims 50-53 differ from the prior art teachings by reciting that the specific binding pair member is a scFv molecule (synthetic Fv). However, the reference teaches that the member of the specific binding pair is a single polypeptide chain comprising a binding domain of an antibody, the binding domain comprises a light chain variable region and a heavy chain variable region (the light chain variable region and a heavy chain variable region are known as Fv molecule). The reference teaches that the genetically diverse population is obtained from a repertoire of artificially rearranged immunoglobulin genes, which would read on the

synthetic Fv molecule. Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a library of nucleic acids encoding synthetic Fv molecule in the recombinant host cells.

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicants disclosure: Dower et al (US Patent 5,427,908) teach recombinant library screening method which uses a bacterial host cell transformed with a bacteriophage expression vector.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams Ph.D., can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0916.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
14 January 2000.